DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

February 16, 2005

**WARNING LETTER NO. 2005-NOL-12**

**FEDERAL EXPRESS**
**OVERNIGHT DELIVERY**

Timothy O. Neilsen, Owner
Neilsen Seafood
16091 Heron Bay Loop Road East
Coden, Alabama 36523-3811

Dear Mr. Neilsen:

On December 13, 14, 16 - 18, 2004, a United States Food and Drug Administration (FDA) investigator inspected your seafood processing facility, located in 16091 Heron Bay Loop Road East, Coden, Alabama. The FDA Investigator issued a Form FDA-483, Inspectional Observations, to you at the conclusion of the inspection which described serious deviations from the Seafood Hazard Analysis Critical Control Points (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your crabmeat is adulterated, as the crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations are as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards reasonably likely to occur and have a HACCP plan listing, at minimum, the critical control points to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for refrigerated, ready-to-eat crabmeat does not list the critical control points of cooking or backing for controlling the food safety hazard of pathogen survival and pathogen growth and toxin formation, respectively.

- You must have a HACCP plan listing, at minimum, the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for refrigerated, ready-to-eat crabmeat does not list a critical limit at the finished product storage critical control point to control pathogen growth and toxin formation. This was brought to your attention in FDA's letter dated May 19, 2004.

- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces, prevention of cross-contamination from unsanitary objects, protection of food, food packaging material, and food contact surfaces from adulteration, use of toxic chemicals, and exclusion of pests with sufficient frequency to ensure control as evidenced by the following:

  - Your firm did not adequately monitor the prevention of cross-contamination from insanitary objects to food as required by 21 CFR 123.11(b)(3). This omission further violates the requirements of 21 CFR 110.10(b)(9). Specifically, employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination. This includes:

    - Employees handled non-sanitized objects and then cooked crabs without washing or sanitizing their hands;

    - Employees wiped their noses/faces then picked crabmeat without washing or sanitizing their hands;

    - Employees contacted residue stained plastic of their stools and then picked crabmeat without washing or sanitizing their hands;

    - An employee's soil stained sleeve routinely contacted live crabs and then cooked crabs during backing operations; and,

    - An employee contacted the rim of his eye glasses then picked crabmeat without washing or sanitizing his hands.

  - You did not monitor the exclusion of pests from the food plant as required by 21 CFR 123.11(b)(8). This omission further violates the requirements of 21 CFR 110.35(c). Specifically, you have not taken adequate measures to exclude pests from the processing areas and protect against the contamination of food on the premises by pests. For example, live flies were observed in the cooking and picking rooms. In addition, at least 25 dead flies were on the window sill approximately six feet from the cooker and the backing table. Spider webs containing dead flies were observed in the cook and picking rooms. The infiltration of flies in your facility was brought to your attention in FDA's letter dated May 19, 2004.

- Your firm did not adequately monitor the protection of food, food packaging material, and food contact surfaces from adulteration with condensate and other biological or physical contaminants as required by 21 CFR 123.11(b)(5). This omission further violates the requirements of 21 CFR 110.20(b). In particular, your facility is not constructed in a manner to prevent condensate from contaminating food, food contact surfaces, and food packaging materials. Cooked crabs and picked crabmeat were stored directly underneath condensate that formed on the ceiling of the cooler and the packing room.

- Your firm did not adequately monitor the conditions and cleanliness of food contact surfaces as required by 21 CFR 123.11(b)(2). This omission further violates the requirements of 21 CFR 110.35(d). Your firm's food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example, an employee used an knife with an ornate handle which contained black residues to pick crabmeat. In addition, the handles of at least three perforated baskets used to store and transfer cooked crabs contained brown residues. Similar conditions were brought to your attention in FDA's letter dated May 19, 2004.

- You have not taken reasonable measures and precautions to ensure persons working in direct contact with food wore appropriate hair nets, headbands, caps, beard covers or other effective hair restraints [21 CFR 110(b)(6)]. For example, a bearded cooking employee did not wear a beard covering when he cooked crabs, and did not wear a head covering when he supplied pickers with ice. Inadequate use of employee hair restraints was brought to your attention in FDA's letter dated May 19, 2004.

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We recognize at the close of the inspection you made a verbal commitment to correct the observed deficiencies; however, we have found deviations from the Seafood HACCP regulation in the previous inspection of your facility. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations.

You should include in your response documentation, such as copies of your revised HACCP plan, temperature monitoring records, or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504)253-4519.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483
21 CFR Parts 110 and 123